

***Paul M. Tarantino Jr., Ph.D.***

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**Professional Experience**

**Pracor Inc.**  
Hartford, MA 01752  
*Director, Safety Pharmacology*

Jan. 2005 to Present

**Pracor Inc.**  
Hartford, MA 01752  
*Associate Director, Safety Pharmacology*

Feb. 2002 to Dec. 2004

- Actively participate on drug development teams, including the design and implementation of the nonclinical safety programs, study design, dosage selection, study initiation and monitoring, report review and finalization, risk assessments, and regulatory interactions.
- Provide the nonclinical safety pharmacology support to multiple development projects and pre-development projects.
- Determine the design and timing of studies, involving the best available relevant consultants and validating new technologies when appropriate.
- Initiate, monitor and report all required studies in time to support project and submission goals.
- Write report summaries and project updates, as needed by the teams and/or management, and prepare relevant parts of regulatory submissions and supporting/defending them at the FDA as needed.
- Support organizational needs of the department and/or the teams according to special skills, opportunities and assignments.
- Be the 'on-call' safety pharmacologist for all projects, consulting to supervisors, physicians, regulatory staff, and program directors.
- Maintain tracking records of all nonclinical toxicology and safety pharmacology studies and results.
- Support Toxicology Department as needed during periods of understaffing (currently toxicologist on one major development program and two research programs).
- Maintain working knowledge of all new and developing regulatory guidances pertaining to nonclinical safety evaluations.
- Involved in the preparation of; annual reports for all development programs, investigator brochures, responses to FDA queries, INDs and three NDAs. Attended Type A, Type C and pre-NDA meetings with FDA.

**Pharmaceutical Synthesis Inc.**  
Hartford, MA 01605  
*Director of Pharmacology*

Feb. 2001 to Feb. 2002

- Directed the research and daily activities of four Ph.D. level scientists in a non-GLP pre-clinical drug research, both for contract and internal research and development. Under my direction these scientists performed routine pharmacokinetic and acute toxicological testing of novel compounds, tested the effects of compounds *in vitro* in a variety of isolated tissues and established models for testing (among others): the effect of compounds on QTc in anesthetized guinea pigs, the effect of compounds on various smooth muscle

responses *in vivo* (including effects on mean arterial pressure, and urinary bladder spasticity), the effect of compounds on erectile function in rats and the effect of compounds on intestinal motility.

- Ultimately responsible for the design and conduct of experiments, correspondence with clients and the writing of reports and grant applications.
- Reported directly to the company President.
- Analyzed and interpreted data accumulated by three staff scientists and one senior scientist using appropriate statistical methods and software and expertise.
- Participated on project teams, presented accumulated data and selected compounds for further study.
- Responsible for report writing for both contract research and internal discovery/research and development projects.
- Presented data at internal and external scientific review committee meetings.
- Developed four *in vivo* models for evaluating the effects of novel compounds on Gram-positive bacterial infection.

**Synthesis Inc.**

March 1998 to Jan. 2001

Worcester, MA 01605

*Staff Scientist then Senior Scientist*

- Directed the research of one to two Ph.D. level scientists.
- Responsible for the design and conduct of experiments, correspondence with clients and writing of reports.
- Participated in writing grant applications.
- Prepared budgets for both grant and contract work.
- Trained new staff in the use of laboratory equipment and techniques.
- Analyzed data accumulated by the pharmacology staff using appropriate statistical methods and software and expertise.
- Participated on project teams, presented data and assisted in the selection of compounds for further study.
- Responsible for report writing for both contract research and the internal discovery/research and development projects.
- Developed guinea pig model for evaluating topical anesthetics.
- Tested the effect of a variety of novel compounds on isolated tissues *in vitro*.
- Performed routine pharmacokinetic and toxicological testing of new compounds (IV, SC, PO, IP, IM).
- Established HPLC conditions and performed HPLC analysis of blood and urine for the presence of parent compound and/or metabolites.
- Developed a model for testing the effect of compounds on mucociliary transport in bovine trachea *in vitro*.
- Developed a model for the testing of antihistamines *in vivo* (croton oil induced ear inflammation).
- Tested the effect of various compounds on human sperm motility *in vitro*.

**University of Massachusetts Medical School**

June 1993 to Feb. 1998

Worcester, MA 01655

*Graduate Research Assistant*

- Trained new technicians and students in the use of laboratory equipment and techniques.
- Analyzed data and designed experiments.
- Participated in the writing of scientific papers and grants.
- Presented work at department seminars and scientific meetings.
- Synthesized a series of N3-substituted 6-anilinouracils.
- Overexpressed and purified DNA polymerase III from two Gram-positive organisms.
- Performed *in vitro* biochemical assays measuring the effect of novel compounds on DNA replication by purified enzymes, in crude extracts and in permeabilized cells.
- Performed *in vitro* assays to measure the antibacterial effect of novel compounds (MICs).

- Performed routine pharmacokinetic and toxicological testing of new compounds (IV, PO, IP).
- Established HPLC conditions and performed HPLC analysis of blood and urine for the presence of parent compound and/or metabolites.
- Performed SDS-PAGE and Western blotting.
- Tested novel compounds in a pneumococcal lung infection model.

### **Additional Responsibilities/Professional Experience:**

- Principal Investigator on a Phase I SBIR grant from the National Institutes of Health (NIH) titled "Hybrid Molecules Designed to Enhance Antibiotic Activity" (Grant No. 1R43GM060828-01). This project advanced and two Phase II applications were submitted and grants awarded, both entitled "Hybrid Molecules Designed to Enhance Antibiotic Activity" (Grant No. 2R44GM060828-02, awarded to P. Tarantino and subsequently assigned to G.E. Wright and Grant No. 5R44GM060828-03 awarded to G.E. Wright)
- Involved in the writing of, and served as the Lead Pharmacologist on additional SBIR grants from NIH for internal research and development projects:
  - "Gram+ Antimicrobials Targeted to DNA Polymerase III", Grant No. 2R44A1041260-02A1, Awarded to G.E. Wright
  - "Drugs to Prevent Recurrent Herpesvirus Infections", Grant No. 2R44A1043170-02, Awarded to G.E. Wright
  - "Novel Drugs to Treat Urinary Incontinence", Grant No. 2R44AG015259-02, Awarded to J. Chen
  - "New Dermal Anesthetics", Grant No. 1R43AR046396-01 and 2R44AR046396-02A1, Awarded to V. Ciofalo
- During time at both UMMS and GLS synthesis, responsible for interactions with the Institutional Animals Care and Use Committee (IACUC) at the University of Massachusetts Medical School. Principal Investigator on approved animal protocols using mice, rats, Guinea pigs and rabbits.
- Attended professional training courses on history and implementation of FDA GLP regulations.
- Attended meetings of the Cardiotoxicity Biomarker Expert Working Group at FDA
- On the roster of the PhRMA Biomarkers and Surrogate Endpoints Work Group

### **Professional Affiliations:**

Safety Pharmacology Society

### **Education:**

University of Massachusetts Medical School, Worcester, MA

1993 to 1998

Ph.D. Pharmacology

Thesis: Development of the Antibiotic Potential of a Unique Family of DNA Polymerase Inhibitors

Villanova University, Villanova, PA

1989 to 1993

B.S. Biology

### **Publications/Presentations:**

H. Barnes, P.M. Tarantino Jr., P. Spacciapoli, N.C. Brown, H. Yu and K. Dybvig, DNA Polymerase III of *Mycoplasma pulmonis*: isolation and characterization of the enzyme and its structural gene, *pol C*, *Molec. Microbiol.* 13, 843-854 (1994)

M. Tarantino, G.E. Wright and N.C. Brown, Novel Antibacterial Agents Targeted against the Gram+ DNA replicase: Effect of N3 Modification on Anti-pol III and Antimicrobial Activity, Annual Meeting of the New England Pharmacologists, February 1996

M. Tarantino Jr., C. Zhi, J. Gambino, G.E. Wright and N.C. Brown, 6-Anilinouracil-based Inhibitors of *Bacillus subtilis* DNA Polymerase III: Antipolymerase and Antimicrobial Structure-Activity Relationships Studied on Substitution at Uracil N3, *J. Med. Chem.* **42**: 11, 2035-2040 (1999)

M. Tarantino Jr., C. Zhi, G.E. Wright and N.C. Brown, Development of Novel Antimicrobials Targeted to DNA Polymerase III of Gram-positive Eubacteria, *Antimicrob. Agents Chemother.* **43**: 8, 1982-1987 (1999)

Schwartz, P. Tarantino, T. Jerussi. (R)-Albuterol and (S)-albuterol exhibit differential effects of mucociliary transport velocity in calf trachea. Poster presentation, Chest Meeting, 2002, San Diego, CA

M. Butler, W.A. LaMarr, K.A. Foster, M.H. Barnes, D.J. Skow, P.T. Lyden, T.L. Bowlin, C. Zhi, Z. Long, A. Manikowski, W.C. Xu, P.M. Tarantino, K.A. Holm, G.E. Wright. Antibacterial Efficacy of Novel Anilinouracil/Fluoroquinolone Hybrids. Poster presentation, ICAAC Meeting 2003, Chicago, IL

Tarantino, N. Appleton, K. Lansdell. Effect of trazodone on hERG channel current and QT-interval. *Eur. J. Pharmacology* **510**: 75-85 (2005)

Zhi, Z. Long, A. Manikowski, N.C. Brown, P.M. Tarantino, K. Holm, E.J. Dix, G.E. Wright, K.A. Foster, M. Butler, W.A. LaMarr, D.J. Skow, I. Motorina, S. Lamothe, and R. Storer. Synthesis and Antibacterial Activity of 3-Substituted-6-(3-ethyl-4-methylanilino)uracils. *J. Med. Chem.* In press.

Schwartz, P.M. Tarantino Jr., T. Jerussi. (S)-Albuterol Negatively Impacts the Mucociliary Transport Effects of (R)-Albuterol *In Vitro*. In preparation

## References:

Available upon request